

REMARKS/ARGUMENTS

This case has been carefully reviewed and analyzed in view of the Official Action dated 15 November 2005. Responsive to the objections and rejections made in the Official Action, Claims 1-10 have been amended to clarify the language thereof.

In the Official Action, the Examiner objected to the Specification due to informalities therein. Accordingly, the Specification and Abstract have been amended and a Substitute Specification and Abstract prepared to replace the Specification and Abstract as filed. The Substitute Specification and Abstract represent clean copies of the amended Specification and Abstract in compliance with 37 C.F.R. § 1.125. The Substitute Specification and Abstract include the same changes that are indicated in the marked-up copy of the Specification and Abstract provided in the "AMENDMENTS TO THE SPECIFICATION." It is believed that the subject matter disclosed by the Substitute Specification was originally disclosed in the Specification and Claims, as filed, and accompanying Drawing Figures. No new matter has been added by the amendment.

In the Official Action, the Examiner objected to Claims 1, 2 and 10 due to informalities therein. In response to this objection, Claims 1, 2 and 10 have been amended to correct any informalities therein.

In the Official Action, the Examiner objected to Claim 2 under 35 U.S.C. § 112, second paragraph, due to the limitation “the plane” having insufficient antecedent basis. In response to this objection, Claim 2 has been amended and now particularly points out and distinctly claims the subject matter which Applicant regards as the invention.

In the Official Action, the Examiner rejected Claims 1, 3-6 and 8-10 under 35 U.S.C. § 102(b) as being anticipated by Silver, et al. (U.S. Patent 5,336,198). Before discussing the prior art relied upon by the Examiner in the rejection, it is believed beneficial to briefly review the subject Patent Application as defined by now amended independent Claim 1. As newly-amended independent Claim 1 now more clearly recites, Applicant’s injection syringe with a seal structure includes among its combination of features, at least one piercing element formed on an inner wall of the hollow barrel. As the Claim further clarifies, “said at least one piercing element pierces said piston thereby preventing re-use of the injection syringe.”

The full combination of these and other features now more clearly recited by newly-amended independent Claim 1 is nowhere disclosed by the cited Silver, et al. reference. Nowhere does the Silver, et al. reference contemplate the idea of “piercing” the piston to compromise the integrity of the syringe thereby preventing re-use. Silver, et al. discloses a manner in which the needle is totally enclosed in the barrel hereby preventing the needle from coming out once it is retracted into

the barrel. Silver, et al. discloses that this method is to prevent re-use and increase safety. However, Applicant teaches an injection syringe that adds an extra feature of safety by incorporating the piercing elements that compromises the integrity of the injection syringe thereby preventing re-use. This is specifically so because once the piston is “pierced”, a hole will be formed in the piston and thus will not prevent leakage of any medicine held within the barrel.

The Silver, et al. reference, nowhere suggests, let alone contemplates the use of piercing elements to precisely form pierced holes within the piston to prevent re-use of the injection syringe. Applicant teaches such a system which adds a level of security to prevent re-use of the injection syringe.

Therefore, as the Silver, et al. reference fails to disclose or suggest, “... at least one piercing element formed on an inner wall of said hollow barrel, wherein said at least one piercing element pierces said piston thereby preventing re-use of the injection syringe ...” as now defined by amended independent Claim 1, it cannot anticipate the invention as now claimed. Further, as the reference to suggest the combination of elements as now claimed, it cannot make obvious that claimed invention.

In the Office Action, the Examiner rejected Claim 2 under 35 U.S.C. § 103(a) as being unpatentable over Silver ('198) in view of Chen (U.S. Patent 6,117,107). In setting forth this rejection, the Examiner acknowledged that Silver, et al. fails to disclose a piercer. The Examiner then cites Chen ('107) as disclosing

an injection device with a piercer (specifically referring to Fig. 5) therein. The Examiner further reasons that it would have been obvious to one of ordinary skill in the art at the time of the invention by the Applicant to modify the injection device of Silver ('198) by adding a piercer of the type suggested by the Chen ('107) reference in order to prevent re-use of the needle. It is believed that the Examiner has misinterpreted the Chen reference system.

Referring to the Chen reference, the element that the Examiner equates to a "piercer" is identified also in Fig. 1 as element 311. Upon examination of the Chen reference, the piercer is referred to as a tenon 311 and is used to couple with the needle unit to pull the needle unit into the barrel after use of the injection syringe.

The Chen reference much in the manner of the Silver, et al. reference does not contemplate the "piercing" of the piston to prevent re-use of the injection syringe. The tenon (piercer) of the Chen reference is formed on the plunger itself, whereas, Applicant teaches the formation of at least one piercing element formed on an inner wall of the hollow barrel. Furthermore, the piercing elements as taught by Applicant pierce the piston itself to prevent re-use, whereas, Chen discloses coupling the needle unit with the tenon 311 that is formed on the plunger to pull the needle unit back into the barrel.

Thus, even if the Silver, et al. reference and the Chen reference are taken alone or in combination, they do not teach, "... at least one piercing element

formed on an inner wall of said hollow barrel, wherein said at least one piercing element pierces said piston thereby preventing re-use of the injection syringe ...”, as is necessary to now amended independent Claim 1.

In the Office Action, the Examiner rejected Claim 7 under 35 U.S.C. § 103(a) as being unpatentable over the Silver, et al. reference in view of Van Dyke (U.S. Patent 6,413,236). In setting forth this rejection, the Examiner acknowledges that Silver, et al. fails to disclose that the fastening seat comprises an axial chamber. The Examiner then cites Van Dyke as disclosing an injection device where the fastening seat comprises an axial channel (specifically referring to Fig. 3). The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention by Applicant to modify the injection device of Silver, et al. by adding a channel to the fastening seat of the type suggested by Van Dyke in order to prevent re-use of the needle.

The Van Dyke reference much in the manner of the Silver, et al. reference and the Chen reference is directed to an automatically retractable needle safety syringe apparatus. The reference, however, fails to disclose or suggest “at least one piercing element” that is used to puncture the piston to prevent re-use of the injection syringe.

Thus, even if the Silver, et al. reference and the Van Dyke reference are taken alone or in combination, they do not teach, “... at least one piercing element formed on an inner wall of said hollow barrel, wherein said at least one piercing

element pierces said piston thereby preventing re-use of the injection syringe ...”,
as is necessary to now amended independent Claim 1.

Additionally, Claims 2-10 are ultimately dependent upon now amended independent Claim 1 and are believed to show patentable distinction over the Silver, et al. reference and the Van Dyke and Chen references when taken alone or in combination.

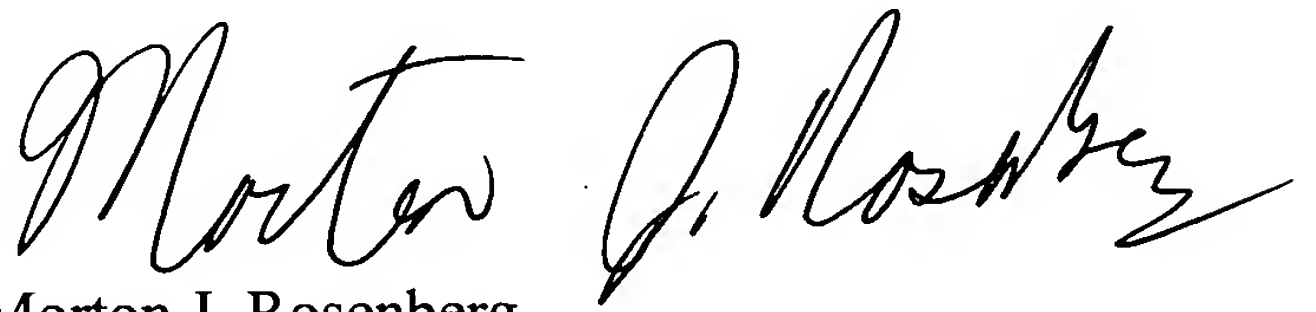
It is not believed by the undersigned Attorney that the combination of the Silver, et al. reference, the Chen reference, or the Van Dyke reference either disclose or suggest a combination of elements which form the invention as now claimed in the subject Patent Application for the purposes and objectives of the Applicant. It is not believed that any of the references either taken alone or in combination anticipate or make obvious the subject Patent Application system as now defined by the amended Claims 1-10.

The references cited by the Examiner but not used in the rejection are believed to be further remote from the subject Patent Application when patentability considerations are taken into account.

MR1035-1286
Serial Number: 10/627,653
Reply to Office Action dated 15 November 2005

It is now believed that the subject Patent Application has been placed in
condition for allowance and such action is respectfully requested.

Respectfully submitted,
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Dated: 14 / Feb. / 2006

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